



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------------------------------------------|-------------|----------------------|---------------------|---------------------|
| 10/507,472 | 09/10/2004 | Davide Bellini | 50294/012001 | 3156 |
| 21559 | 7590 | 02/11/2008 | EXAMINER | |
| CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110 | | | | KRISHNAN, GANAPATHY |
| ART UNIT | | PAPER NUMBER | | |
| | | 1623 | | |
| NOTIFICATION DATE | | DELIVERY MODE | | |
| 02/11/2008 | | ELECTRONIC | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

| | | | |
|------------------------------|---------------------------------------|-------------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/507,472 | BELLINI ET AL. | |
| | Examiner Ganapathy Krishnan | Art Unit 1623 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 18 June 2007.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-36 and 38-47 is/are pending in the application.
- 4a) Of the above claim(s) 14-36,38-42 and 47 is/are withdrawn from consideration.
- 5) Claim(s) 1-13 is/are allowed.
- 6) Claim(s) 43-46 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed 6/18/2007 has been received, entered and carefully considered.

The following information provided in the amendment affects the instant application:

1. Claim 37 has been canceled.
2. Claims 6, 8-9, 11 and 44 have been amended.
3. Remarks drawn to objections and rejections under 35 USC 112, first and second paragraphs.

Claims 1-36 and 38-47 are pending in the case. Claims 14-36, 38-42 and 47 have been indicated as withdrawn. The action below is for claims 1-13 and 43-46, which are currently under prosecution.

Specification

The objection to the specification (abstract) has been overcome by filing an Abstract on a separate sheet of paper.

Claim Objections

The objections to Claims 8-9 have been overcome by amendments.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of Claims 1, 4-12 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an ester of hyaluronic acid formed between the carboxyl group of the hyaluronic acid and the compound of formula (I) having the groups hydroxy, alkyloxy having an alkyl chain C1-C20 bearing one or more hydroxy groups, heterocycle bearing one or more hydroxy groups for R and hydroxy, alkyl C1-C2- substituted with one or more hydroxy and alkyloxy C1-C20 substituted with one or more hydroxy for R1-R3, does not reasonably provide enablement for the said ester for the said substitutions being hydrogen and the alkyl, heterocycle and alkyloxy groups without hydroxy substitutions, has been overcome in view applicants arguments. The enablement rejection is being maintained for claim 44.

Applicants have amended claim 44 to recite, an anti-inflammatory drug or metalloprotease inhibitor or a NO-synthase inhibitor or other biologically active molecules. These are general classes of agents comprising of several individual agents in each class. Also, the terms, biologically active molecules, is very broad and is seen to include several compounds. The term biologically active is purely a functional distinction that reads on any known or unknown compounds that might have the recited functions. The specification, at page 7, lines 23-26, does not provide a definition for the said terms.

The rejection is being maintained

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of Claims 1, 4-12 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, has been overcome in view of applicants arguments.

The rejection of claims 43-46 is being maintained for reasons of record.

Applicants have argued that the terms, 'aqueous solution', in claim 43 is water having dissolved species. It is not clear what all are included by the term, species that applicants intend. In the absence of a clear recitation as to what all are intended, the claim is rendered indefinite.

Conclusion

1. Claims 43-46 are rejected.
2. Claims 1-13 are seen to be free of prior art.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GK



Shaojia A. Jiang
Supervisory Patent Examiner
Art Unit 1623